MAY 2 4 2006

510(K) Summary

K051442

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	June 1, 2005
Device Trade Name:	PhotoSilk Plus Pulsed Light System and Laser Attachment
Common Name:	Pulsed Light System. Laser: Er:YAG laser, Nd:YAG laser, Q-Switched Nd:YAG laser.
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	StarLux Pulsed Light System, CO3 Er:YAG laser, ESC Nd:YAG Accessory, and Medlite C6 Q-Switched Nd:YAG laser
Device Description:	The PhotoSilk Plus Pulsed Light System and Laser Attachment provides 400-1200nm pulsed light, 2,940nm Er:YAG, 1064nm Nd:YAG and 1064nm Q-Switched Nd:YAG wavelengths. Laser emission activation is by foot switch. Electrical requirement is 220 VAC, 20A, 50-60 Hz, single phase.
Intended Use:	The PhotoSilk Plus Pulsed Light System is intended for permanent hair reduction, and the treatment of vascular and pigmented lesions, facial and leg veins, and inflammatory acne. The PhotoSilk Plus Pulsed Light System Laser Attachment is intended for: 2,940 nm - for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues. 1,064 nm - for treatment of benign cutaneous vascular lesions, pigmented lesions, and hair removal. QS 1,064 nm - for tattoo removal, and the treatment of pigmented lesions.
Comparison:	The PhotoSilk Plus Pulsed Light System and Laser Attachment have very similar indications for use, the same principle of operation, and similar performance specifications as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The PhotoSilk Plus Pulsed Light System and Laser Attachment is a safe and effective device for the indications specified.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

Cynosure, Inc.
% Mr. George Cho
Senior Vice President
5 Carlisle Road
Westford, Massachusetts 01886

Re: K051442
Trade/Device Name: Cynosure PhotoSilk Plus Pulsed Light System Laser Attachment
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 2, 2006
Received: February 3, 2006

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

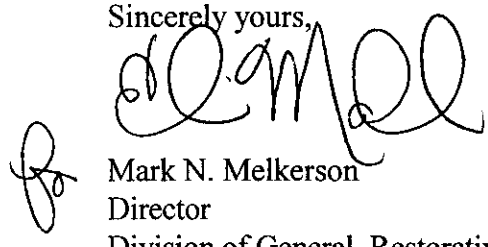
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051442

Device Name: Cynosure PhotoSilk Plus Pulsed Light System Laser Attachment

Indications For Use:

The PhotoSilk Plus Pulsed Light System is intended for permanent hair reduction and the treatment of dermatological vascular lesions, facial and leg veins, benign pigmented lesions, and inflammatory acne.

The PhotoSilk Plus Pulsed Light System Laser Attachment is intended for:
Er:YAG 2,940 nm - for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues.

Long Pulse Nd:YAG 1,064 nm - for the treatment of vascular lesions, pigmented lesions, wrinkles and for permanent hair reduction..

Q-Switched Nd:YAG 1,064 nm - for dark tattoo removal, and the treatment of pigmented lesions.

Prescriptive Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051442